510(K) SUMMARY

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Regulatory Affairs

DATE PREPARED: May 28, 2010

DEVICE TRADE NAME: BD Directigen™ EZ Flu A+B assay

DEVICE COMMON NAME: Influenza virus serological reagents

DEVICE CLASSIFICATION: 21 CFR 866.3330

PREDICATE DEVICES : BD Directigen™ EZ Flu A+B assay
(k063689) and (k042472)

INTENDED USE :

The BD Directigen™ EZ Flu A+B assay is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral antigens from nasopharyngeal washes/aspirates, nasopharyngeal swabs and throat swabs of symptomatic patients. The Directigen™ EZ Flu A+B assay is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. All negative test results should be confirmed by cell culture because negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

DEVICE DESCRIPTION :

The Directigen EZ Flu A+B test is a chromatographic assay to qualitatively detect influenza A and B viral antigens in samples processed from respiratory specimens. When specimens are processed and added to the test device, influenza A or B viral antigens bind to anti-influenza antibodies conjugated to visualizing particles in the
corresponding A and B test strips. The antigen-conjugate complex migrates across the test strip to the reaction area and is captured by the line of antibody on the membrane. A positive result for influenza A is visualized as a reddish purple line at the Test "T" position and the Control "C" position in the Directigen EZ Flu A read window. A positive result for influenza B is visualized as a reddish purple line at the Test "T" position and the Control "C" position in the Directigen EZ Flu B read window.

DEVICE COMPARISON:

The modified kit differs from the currently marketed BD Directigen™ EZ Flu A+ B kit in the following way:

The controls have been changed from liquid to dry swabs.

SUBSTANTIAL EQUIVALENCE:

The modified device BD Directigen™ EZ Flu A+ B is substantially equivalent to the current legally marketed device, BD Directigen™ EZ Flu A+B assay.

Modifications are as follows:

Modification	Potential Impact of Modification
Change of control from Liquid to dry swab.	Dry controls are more stable than liquid controls. Use of dry control swabs allows for optimal inventory management during viral outbreaks are also supplied by most competitors. Additionally, rare customer complaints regarding control failures have been attributed to improper processing (protocol not followed, processing agent not added to liquid control). This possibility is eliminated by conversion to dry swab controls. Dry swabs controls are also supplied by most competitors. Dry swabs may not perform like liquid controls or be as stable. Stabililty and swab performance studies will define stability and performance characteristics of the swabs.

Included in the Special 510(k) are the Hazard Analysis and the associated validations and verifications conducted to address individual hazards/risks identified for this modification. The Hazard Analysis did not identify any changes that raised new issues of safety and effectiveness. The parameters listed below were evaluated in studies performed according to appropriate Design Control procedures. The modified BD Directigen™ EZ Flu A+ B assay met all current product claims for performance.

Parameter	Result
Dry swabs controls must be comparable in stability to current liquid controls	Data to date from accelerated stability studies have indicated 30 months at 2-30*C. Confirmatory real time stabilities have indicated 5 months at 2-30*C. Real time stabilities will continue.
Dry swabs controls must perform in the assay comparable to the current liquid controls	Dry swabs perform comparably in the assay to the current liquid controls.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

JUN 14 2010

Becton Dickinson and Company
Gregory P. Payne
Director, Regulatory Affairs and Quality Systems
11085 North Torrey Pines Rd, Suite 210
La Jolla, CA 92037

Re: k101529
Trade/Device Name: BD Directigen EZ Flu A + B Assay
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza Virus Serological Reagents
Regulatory Class: Class I
Product Code: GNX
Dated: May 28, 2010
Received: June 2, 2010

Dear Mr. Payne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.
Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does

not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, Ph.D.
Director, Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE

510(K) Number (if known) k101529

Device Name: BD Directigen™ EZ Flu A+B assay

Indication for Use:

The BD Directigen™ EZ Flu A+B assay is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral antigens from nasopharyngeal washes/aspirates, nasopharyngeal swabs and throat swabs of symptomatic patients. The Directigen™ EZ Flu A+B assay is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. All negative test results should be confirmed by cell culture because negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

Prescription Use__X__ And/or Over the Counter Use____
21 CFR 801 Subpart D) (21 CFR 801Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k101529